UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Case Number 15-cv-2210 PJS/BRT

RONALDO LIGONS,
BARRY MICHAELSON,
JOHN ROE, and JANE ROE,
JOHN MILES AND JANE MILES,
JOHN STILES AND JANE STILES,
individually, and on behalf of those similarly situated,

Plaintiffs,

v.

MINNESOTA DEPARTMENT OF CORRECTIONS,
THOMAS ROY,
DR. DAVID A. PAULSON, M.D.,
NANETTE LARSON,
Dr. D. QUIRAM, M.D.,
Dr. R. HANSON, M.D.,
JOHN and JANE DOES A - J,
and
CENTURION OF MINNESOTA, L.L.C.,
Defendants.

PLAINTIFF'S RULE 26(a)(2)(D) DISCLOSURES

COMES NOW the above named PLAINTIFFS, by and through undersigned counsel, hereby file this Rule 26(a)(2)(D) Expert Opinion disclosure, as follows:

REBUTTAL DECLARATION

1. **Background and Credentials:** My name is Dr. Julie Thompson, I am a medical doctor specializing in hepatology and gastroenterology at the University of Minnesota Hospitals and have submitted a Declaration and Opinion in the above captioned matter. The following is a Rebuttal Declaration in response to the Report of Dr.

Newton Kendig.

2. **Sources Relied Upon in Preparation of Rebuttal Declaration:**

A. Dr. Newton E. Kendig: Expert Report on Treating Chronic Hepatitis C Virus (HCV) Infection in the Correctional Setting in 2016.

B. "When and in Whom to Initiate HCV Therapy" AASLD/IDSA HCV Guidelines, July 6, 2016. *www.hcvguidelines.org* (accessed November 18, 2016)

C. Contract #70449 Between the Minnesota Department of Corrections (DOC) and Medical Care Contractor (Centurion of Minnesota)

D. Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations from the Department of Veterans Affairs National Hepatitis C Resource Center Program and the HIV, Hepatitis, and Public Health Pathogens Programs in the Office of Patient Care Services , Updated: September 22, 2016

Contract #70449

The "Correctional" Standard of Care

3. I am informed by counsel that, Section 32 and Attachment 1, sections (H) and (P) of current contract #70449 between the Minnesota Department of Corrections (DOC) and medical care Contractor (Centurion of Minnesota) reads as follows:

> **32. Pharmaceutical formulary:**
>
> 32.1 The DOC will have the right to approve the pharmaceutical formulary and any subsequent modifications, exceptions, or denials related to this formulary. Discussion regarding the formulary will occur at the Pharmaceutical and Therapeutics Committee meetings on an as needed basis. The final decision to include or exclude medications on the formulary will be the DOC's.
>
> 32.2. The CONTRACTOR will develop a mutually agreed upon non-formulary review process for all non-formulary medications prescribed by the CONTRACTOR's practitioners. This process will include the timely clinical pharmacist review of non-formulary prescriptions with associated clinical justification; verbal contact with prescriber by clinical pharmacist to

clarify any predisposing clinical issues; education of the prescriber to formulary alternatives, where appropriate; and referral to the CONTRACTOR's Regional Medical Director when additional inquiry is indicated. The non-formulary review process will be initiated by the prescribing practitioner and forwarded to the clinical pharmacist upon completion of required clinical justification. In the event that the non-formulary prescription order is changed to a formulary alternative, prescriber will discontinue previously ordered non-formulary prescription in the medical record, either personally or by verbal order to nursing staff. (emphasis added)

Attachment 1: On Site Services

H. HIV SERVICES

The CONTRACTOR (*i.e.* Centurion) shall provide all treatment of HIV/AIDS in a manner consistent with applicable standards of medical care, including CDC guidelines and Twin Cities' area community standard of care... (emphasis added)

P. HEPATITIS C TREATMENT

The CONTRACTOR (*i.e.* Centurion) shall provide services for the diagnosis and treatment of Hepatitis C within the then current guidelines and the current Hepatitis C treatment protocols established by the DOC, as incorporated herein by reference for the diagnosis and treatment protocols· established by the DOC, as incorporated herein by reference. This includes requirements perform liver biopsies, lab tests, medications, and ·psychiatry, and may change from time-to-time at the discretion of the DOC (emphasis added.

4. Paragraph 32 of the Contract, and paragraphs H. and P. (above) apparently permit the DOC or its Medical Director to refuse to fill prescriptions written by "prescribing practitioners" without regard to the medical community standard of care for the treatment of HCV, or other medical conditions, except for HIV/AIDS.

5. My terms of engagement were to offer an opinion regarding the Twin Cities "medical community" standard of care for the diagnosis and treatment HCV infection, as determined by international medical professional societies and the medical profession generally, including the American Association for the Study of Liver Disease (AASLD),

and the Infections Disease Society of America (IDSA) Guidelines (*www.hcvguidelines.org*.) which have been adopted by the Centers for Disease Prevention and Control (CDC) as the government agency authority on this topic,

6. The medical community standard of care referenced in the contract paragraph H. as applying to HIV/AIDS, applies to the medical standard of care applicable to patients whether imprisoned or not. This is the same standard of care I was engaged to apply to the treatment of HCV in my opinion in this case.

7. Medical care dependent upon the protocols of a "corrections department" as referenced in paragraph P., that may change "from time-to-time at the discretion of the DOC," is not a "medical community" standard of care and is not a matter for medical expert opinion.

8. However, the above contract demonstrates the DOC understands that prison medical care providers must meet the same standards of medical care required by the CDC and the Twin Cities medical community for prisoners as would apply outside of prison, at least in the diagnosis and treatment of HIV/AIDS.

9. To the best of my knowledge there is no separate "correctional standard of care" recognized by the medical profession for HCV. Both HIV/AIDS and HCV require treatment according to the medical community standard of care; and not the medical community standard of care for one infectious blood-borne disease, and DOC protocols for the other.

10. Dr. Kendig states he was engaged to determine if Minnesota DOC are consistent "with the *correctional standard of care* for the management of inmates with chronic HCV

infection in 2016." (p. 4, para. 1).

11. The "correctional standard of care" is not a medical standard of care with which I am familiar, nor have I heard it used within the medical profession. It implies that some patients may receive differing standards of medical care depending on their incarceration status.

12. I recently attended the annual AASLD international conference "The Liver Meeting" with nearly 10,000 physicians specializing in liver disease. It is the largest meeting of its kind in the world. The topics included numerous presentations on the medical advantages of early treatment of HCV with direct acting anti-viral (DAA) drugs, including for fibrosis scores of F0-F1, in order to prevent progression of liver fibrosis and transmission of HCV infection.

13. To the best of my knowledge, a "correctional standard of care" that justifies delaying treatment of HCV infections based on institutional cost-saving was not on the agenda among hundreds of presentations and would be contrary to the trends in treatment recommended at the meeting. Rather, the cost-effectiveness of early treatment to avoid liver transplantation and more serious complications of HCV was discussed,

14. The following comments parallel the structure of Dr. Kendig's Report for the convenience of the Court.

A. Clinical Overview of Chronic HCV Infection (pp. 6-10)

15. Dr. Kendig confirms many particulars in my own opinion regarding the need for HCV screening and treatment in prisons, including:

HCV Transmission

16. HCV is a blood-borne pathogen. It can be spread by injection drug use, or any other blood exposure including possibly through sharing razors, sexual contact that includes blood exposure (particularly between men), and unsanitary needles/tattoos; all of which are more common in the prison population than the general population.

Prevalence of HCV Infection in a Correctional Setting

17. The high prevalence of HCV in prison populations (9.6 to 41.1% according to some of the data cited by Dr. Kendig) makes incarceration, *itself,* one of the AASLD/IDSA risk factors for HCV testing, and uninfected prisoners may risk HCV infection from other inmates.

Screening for HCV Infection

18. Dr. Kendig notes the reasons for screening "at risk" groups includes anyone with a history of injection drug use and adults born between 1945 and 1965. The AASLD/IDSA identifies many more risk groups for screening, which apply to prison populations:

(AASLD/IDSA) Recommendations for One-time HCV Testing

- One-time HCV testing is recommended for persons born between 1945 and 1965, without prior ascertainment of risk.
- Other persons should be screened for risk factors for HCV infection, and one-time testing should be performed for all persons with behaviors, exposures, and conditions associated with an increased risk of HCV infection.

1. *Risk behaviors*
   - Injection-drug use (current or ever, including those who injected once)
   - Intranasal illicit drug use

   Risk exposures
   - Persons on long-term hemodialysis (ever)
   - Persons with percutaneous/parenteral exposures in an unregulated setting

- Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-infected blood
- Children born to HCV-infected women
- Prior recipients of transfusions or organ transplants, including persons who:
  - Were notified that they received blood from a donor who later tested positive for HCV infection
  - Received a transfusion of blood or blood components, or underwent an organ transplant before July 1992
  - Received clotting factor concentrates produced before 1987
- Persons who were ever incarcerated

Other considerations

- HIV infection
- Sexually active persons about to start pre-exposure prophylaxis (PreP) for HIV
- Unexplained chronic liver disease and/or chronic hepatitis including elevated alanine aminotransferase levels
- Solid organ donors (deceased and living)[1]

Being incarcerated, itself, is a risk-factor for being exposed to HCV according to the AASLD/IDSA (to which the Centers for Prevention and Disease Control (CDC) and U.S. Preventative Services Task Force (USPTF) defer regarding HCV matters.)

Natural History of Chronic HCV Infection

19. Dr. Kendig *also* confirms many particulars in my own opinion regarding the need for evaluation of *all* HCV-positive inmates "to determine if they have liver disease and to assess its severity", including:

> a. all persons diagnosed with HCV infections should be evaluated to determine the severity of their liver disease, if any, using the METAVIR score F0 through F4 to

[1] "When and in Whom to Initiate HCV Therapy" AASLD/IDSA HCV Guidelines, July 6, 2016. *www.hcvguidelines.org* (accessed November 18, 2016) (emphasis added).

determine the level of fibrosis (i.e. scarring) of the liver. (p. 7, para. 3-4).

b. the use of several of non-invasive tests, including imaging elastography to assess the degree of fibrosis in addition to blood tests. There is no indication in the records of Ronaldo Ligons and Barry Michaelson that I have examined to suggest that imaging elastography is offered to MN DOC inmates infected with hepatitis C virus, contrary to Dr. Kendig's recommendation to assess the degree of fibrosis.

c. Dr. Kendig also confirms that DAAs cure most HCV-positive patients with 12 weeks of oral medications and that these medications are the medical community standard of care, *i.e.* :

> The AASLD (American Association for the Study of Liver Disease and IDSA (Infectious Disease Society of America) recommend that nearly all persons with chronic HCV infection be considered candidates for treatment with DAAs due to the multiple patient benefits and public health advancements associated with curing HCV infection." (p. 8, para. 4)

Costs of DAA Regimens and Cost Effectiveness and Affordability

20. Dr. Kendig cites additional language in the AASLD/IDSA Guidelines which leads him to consider: (a) *Costs of DAA Regimens to Treat Chronic HCV Infection*; and (b) *Cost Effectiveness and Affordability of Treating Chronic HCV Infection with DAA Therapies* (p. 9). However, neither "cost" nor "cost effectiveness," as described by Dr. Kendig, are relevant to the *prescribing decision* of the medical practitioner when treating a life-threatening illness, HCV, with curative, life-saving medication.

21. The role of the physician is to prescribe medication appropriate to treat the patient. The third party insurer or pharmaceutical benefits provider must determine whether

payment for prescription will be covered (and to what extent) as a budgetary matter. These are not medical questions bearing on the suitability of DAAs for treatment of any particular patient infected with HCV.

22. After the initial approval of DAAs as the standard of care in late 2013, the AASLD/IDSA specifically rejected "prioritizing" by treating providers as the new medications became more available. The AASLD/IDSA HCV Guidance Panel explicitly recommended, without reservation, that all HCV treatment practitioners prescribe the DAA drugs for all HCV positive patients without prioritization from a medical standpoint:

> Successful hepatitis C treatment results in sustained virologic response (SVR), which is tantamount to virologic cure, and as such, is expected to benefit nearly all chronically infected persons. When the US Food and Drug Administration (FDA) approved the first IFN-sparing treatment for HCV infection, many patients who had previously been "warehoused" sought treatment, and the infrastructure (experienced practitioners, budgeted health-care dollars, etc) did not yet exist to treat all patients immediately. Thus, the panel offered guidance for prioritizing treatment first to those with the greatest need. Since that time, there have been opportunities to treat many of the highest-risk patients and to accumulate real-world experience of the tolerability and safety of newer HCV medications. More importantly, from a medical standpoint, data continue to accumulate that demonstrate the many benefits, within the liver and extrahepatic, that accompany HCV eradication. Therefore, the panel continues to recommend treatment for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. Accordingly, prioritization tables are now less useful and have been removed from this section.[2]

23. According to the AASLD/IDSA HCV Guidelines, patients at all five levels of METAVIR Score F0 to F4 benefit from achieving sustained viral response (SVR) and

[2] "When and in Whom to Initiate HCV Therapy" AASLD/IDSA HCV Guidelines, July 6, 2016. *www.hcvguidelines.org* (accessed November 18, 2016) (emphasis added).

delaying treatment for HCV provides to no benefits to the patient, since there are no significant side-effects associated with direct acting anti-viral (DAA) medications.

B. Screening, Evaluation, and Treatment of Inmates with Chronic HCV Infection in the Correctional Setting, (pp. 10-16)

24. From a medical standpoint, I am not able to offer an opinion on the Supreme Court case, *Estelle v. Gamble,* or its implications for this case. This is a matter for the Court.

25. However, I am not aware that the standard of care for medical treatment providers differs between the medical treatment appropriate for prisoners, and that for non-prisoners as Dr. Kendig asserts in his Report. He acknowledges the importance of medical subspecialty organizations, the AASLD and IDSA, for establishing clinical guidance for HCV practitioners (p. 10, para. 3).

26. Dr. Kendig acknowledges that universal screening of inmates is already taking place in some state prisons systems, and we agree that, at a minimum, inmates should be tested: (a) at intake when self-identifying for AASLD/IDSA risk factors including being born between 1945 and 1965; (b) when identified as HCV positive in a clinical setting; and, (c) upon request. (p. 11, para. 4). From a public health standpoint universal testing and annual screening is optimal, because incarceration, itself, is identified by AASLD/IDSA as a risk factor for HCV infection.

27. To the extent that the Federal Bureau of Prisons (FBOP) guidelines state that DAA drugs are the standard-of-care for treating all HCV-positive inmates, with which Dr. Kendig apparently agrees, I have no dispute regarding this as standard of care, *i.e.*

The current FBOP guidelines state the use of DAA therapies is the standard of care for treating inmates with chronic HCV infection.... (Kendig quote, p. 12. para. 3)

28. Dr. Kendig states that FBOP prioritizing treatment of inmates into categories described on page 13 of his Report are largely due to financial reasons and, as non-medical matters, are beyond my medical expertise. According to Dr. Kendig:

> For most state correctional systems and the FBOP the immediate treatment of all inmates with HCV infection with the newly available DAA therapies is fiscally unaffordable with existing budgets.... and is of questionable cost effectiveness for inmates with absent or minimal liver disease. (p. 14, para. 1)

29. "Affordability" and "cost effectiveness" are not relevant to the medical standard of care for the treatment of HCV or other medical conditions, as far as I am aware. These are not medical considerations in deciding whether to issue a prescription for an HCV-positive patient, or not.

30. In his concluding paragraph, Dr. Kendig offers the following opinion:

> The Minnesota DOC guidelines for treating inmates with chronic HCV infection are medically appropriate, consistent with the correctional standard of health care, and are not deliberately indifferent to the medical needs of inmates generally. (p.16, para. 1).

31. After having interviewed Mr. Ligons and Mr. Michaelson; having reviewed the medical charts of each; and having written the appropriate prescriptions for DAA drugs to cure both of HCV infections according to the medical community standard of care for treating inmates with chronic HCV infections, it is possible to offer an opinion that differs from Dr. Kendig in the treatment of individual patients in this case.

32. "*Correctional* standard of care" and "deliberate indifference to the needs of inmates *generally*" are not medical terms with which I am familiar from my medical training, from

guidelines published by the AASLD/IDSA regarding the diagnosis and treatment of HCV or other professional medical bodies. If this language has legal meaning that is for the Court to decide.

33. With respect to the treatment of chronic HCV infections in individual patients, the medical community standard of care is, as Dr. Kendig agrees, treating patients with the DAA therapies (see #25 above). These are the medications that Declarant prescribed for Mr. Ligons and Mr. Michaelson, given the current state of medical science.

34. Consideration of "inmates generally" is not properly part of the decision to treat any particular individual inmate but, rather, is a description of institutional policy. From a medical standpoint, each patient must be individually examined, evaluated and prescribed the appropriate medication for the patient's particular condition. This is always the case.

35. The medical community standard of care requires that treating physicians prescribe DAAs to all HCV-positive patients irrespective of fibrosis level to cure the infection and to prevent spread of the disease to others.

36. This is also the standard of care adopted by the Veteran's Administration which explicitly seeks to treat all HCV-positive veterans, including METAVIR F0-2:

> All patients with chronic HCV who do not have medical contraindications are potential candidates for antiviral treatment. Patients with advanced liver disease are likely to derive the greatest benefit from treatment... Patients with mild liver disease (METAVIR F0-2) have less urgency for treatment in the short term, but should be informed of current treatments and the potential to cure HCV. Patients with mild liver disease (METAVIR F0-2) and no extra-hepatic manifestations can be treated in the near term if the patient desires treatment and is otherwise a candidate for HCV treatment. [3]

[3] Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations from the Department of Veterans Affairs National Hepatitis C Resource Center Program and the

Cost of the treatment is not part of the medical decision whether to write the prescription to cure the patient and prevent the spread of an infectious disease. To my knowledge, the prison budget is an administrative matter, not a medical question that should permit the reduction of the medical community standard of care for prescribing medical treatment for a life-threatening but curable disease.

37. It is my opinion that the Twin Cities medical community standard of care applies to doctors treating DOC inmates with HCV as well HIV/AIDS and other medical conditions.

C. Assessment of Minnesota Department of Corrections (DOC) Guidelines for Screening and Treating Inmates with Chronic HCV Infection

38. The Minnesota DOC screening Guidelines for HCV Infection of January 2016, the statistical and other data referenced by Dr. Kendig indicate that the Minnesota DOC has begun to take steps that can result in advances in HCV treatment program, making DAA drugs "available" to treat some HCV-positive patient-inmates based on a "case by case review of treatment candidates by the DOC Medical Director," who is not the "prescribing practitioner" (as described in Section 32.2 of the DOC-Centurion CONTRACT). This does not meet the AASLD/IDSA standard of care, which would be to screen all inmates, and to treat all HCV-positive inmates.

39. The current Minnesota DOC Guidelines do not treat all HCV-infected inmates with the DAA drugs and do not meet the AASLD/IDSA standard of care for the individual patients who are HCV-positive, to cure individual HCV infections, prevent progression of liver damage, reduce liver cancer and to prevent the transmission of the disease to other inmates and persons in the general population when DOC inmates are released.

HIV, Hepatitis, and Public Health Pathogens Programs in the Office of Patient Care Services Updated: September 22, 2016, p. 12.

40. Limiting HCV treatment to patients with METAVIR F3-F4 or F2 with HIV or HBV co-infections, at the discretion of the Medical Director, ignores a large number inmates who are as infectious as those theoretically eligible for treatment. As a doctor specializing in gastroenterology and hepatology, and as a doctor who has tested and treated hepatitis C patients at the University of Minnesota Hospitals, I must add the following: (a) to wait to treat a hepatitis C patient with a METAVIR score under 3 is to subject the patient to unnecessary suffering, degradation of the patient's health, and foreseeable shortening of the patient's life, in a manner incompatible with the AASLD/IDSA community standard of care for treatment of hepatitis C patients and the Hippocratic Oath; (b) to wait to treat a hepatitis C patient with a METAVIR score under 3 is to subject the patient to a foreseeable outcome of a liver transplant, which costs approximately $500,000 in the first year alone, in comparison to the maximum of charge of $94,500 for 12 weeks of daily Harvoni medication, or $75,000 for the reported 20% discount obtained by Centurion of Minnesota, LLC, or approximately $50,000 for Minnesota Medical Assistance recipients; and (c) as cited by the AASLD/IDSA, the cost to save a life of one formerly infected by hepatitis C decreases with each cured patient.

41. According to Dr. Kendig's data, 76% of new male inmates and 88% of new female inmates were tested for HCV infection in the fourth quarter of FY 2016 at the State's two major intake institutions. If these percentages are reflective of testing for all of FY 2017, universal testing appears to be within reach. (p. 15, para. 1)

42. Dr. Kendig also endorses the use of ultrasound imaging (e.g. FibroScan) in diagnosis, and the AASLD/IDSA recommends "the most efficient approach to fibrosis assessment is

to combine direct biomarkers and vibration-controlled transient liver elastography" where it is available. Both are available in the Twin Cities.

43. Dr. Kendig *also* confirms many particulars in my own opinion regarding the need for evaluation of *all* HCV-positive inmates "to determine if they have liver disease and to assess its severity", including:

a. all persons diagnosed with HCV infections should be evaluated to determine the severity of their liver disease, if any, using the METAVIR score F0 through F4 to determine the level of fibrosis (i.e. scarring) of the liver. (p. 7, para. 3-4).

b. the use of several of non-invasive tests, including imaging elastography to assess the degree of fibrosis in addition to blood tests.

44. There is no indication in the records of Ronaldo Ligons and Barry Michaelson that I have examined to suggest that imaging elastography is offered to MN DOC inmates infected with hepatitis C virus, contrary to Dr. Kendig's report.

45. The MN DOC guidelines for treating inmates with chronic HCV infection do provide limited, selective access to DAA therapies that are recommended by the AALSD and IDSA guidelines, but the MN DOC guidelines, as described by Dr. Kendig, do *not* require the DOC or its Medical Director to provide all HCV-positive patients with access to the DAA therapies as recommended by the AALSD and IDSA, which is the standard of care in the HCV medical treatment community in the Twin Cities, nationally and internationally.

46. Dr. Kendig's Report does not speak to the number of those inmates tested and found to be HCV-positive at various METAVIR levels, and the number of patients for whom the

DOC Medical Director used his discretion to treat with the DAA drugs that are theoretically available, pursuant to the DOC guidelines, and whether "prescribing practitioners" are permitted to submit prescriptions for the DAA drugs by their employer, under the DOC Contract.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: November 29, 2016

Julie Thompson MD
(electronically signed)

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Reviewed and signed in accordance with Fed. R. Civ. P. 11 and Minn. Stat. §549.211.

Date: 29 November 2016

Respectfully:

PETER J. NICKITAS LAW OFFICE, L.L.C.

/s/ *Peter J. Nickitas* (electronically signed)

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